PEPPER HAMILTON LLP
301 Carnegie Center, Suite 400
Princeton, NJ 08543-5276
Phone: (609) 452-0808
Fax: (609) 452-1147

*Attorneys for Plaintiff*
Eli Lilly and Company

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| **ELI LILLY AND COMPANY**<br>**Plaintiff,**<br>**v.**<br>**ZYDUS PHARMACEUTICALS USA, INC.**<br>**Defendant.** | **Civil Action No.** |

**COMPLAINT**

Plaintiff Eli Lilly and Company ("Lilly") files this Complaint against Zydus Pharmaceuticals USA, Inc. ("Zydus") for breach of this Court's Consent Judgment and Order entered in Case 2:07-cv-03770 on December 12, 2007 (the "2007 Consent Order"), and under 35 U.S.C. § 271(e)(2) for patent infringement. This action concerns Lilly's patent on its pharmaceutical drug product Strattera®. Plaintiff, Lilly, hereby alleges as follows:

**Parties, Jurisdiction, and Venue**

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business

of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Upon information and belief, Defendant Zydus is a corporation organized under the laws of New Jersey having a principal place of business at 506 Carnegie Center, Princeton, New Jersey 08450.

3. This Court has personal jurisdiction over Zydus by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey.

4. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

5. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

**Plaintiff's Strattera® Products and Related Patent**

6. On August 19, 1997, United States Patent No. 5,658,590 (the "'590 patent"), entitled "Treatment of Attention-Deficit/Hyperactivity Disorder," was duly and legally issued to John H. Heiligenstein and Gary D. Tollefson and assigned to Lilly. A true and correct copy of the '590 patent is attached hereto as Exhibit 1. The '590 patent claims methods of treating attention-deficit/hyperactivity disorder with tomoxetine. Tomoxetine is now known as atomoxetine. The '590 patent expires on November 26, 2016.

7. Strattera® is the brand name for the commercial formulation of atomoxetine hydrochloride developed, manufactured, and sold by Lilly. Lilly submitted a New Drug

Application to the FDA for Strattera® Capsules for the treatment of attention-deficit/hyperactivity disorder (NDA No. 21-411). NDA No. 21-411 was approved by the FDA on or about November 26, 2002, for Strattera® Capsules in strengths of Eq 10 mg, 18 mg, 25 mg, 40 mg, and 60 mg. Strattera® Capsules in strengths of Eq 80 mg and 100 mg were approved on or about February 14, 2005.

8. The Food and Drug Administration Center for Drug Evaluation And Research Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") lists the '590 patent for each of the strengths of Strattera® approved by the FDA under NDA No. 21-411.

9. Pursuant to 21 U.S.C. § 355a, Lilly is entitled to a six-month period of pediatric exclusivity for Strattera® beyond the date of expiration of the '590 patent.

**Zydus' ANDA Filing**

10. By a letter dated March 24, 2011 (the "Zydus Notice Letter"), Zydus notified Lilly that Zydus had submitted ANDA No. 79-017 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Zydus ANDA"). On information and belief, the Zydus ANDA seeks approval to engage in the commercial manufacture, use, or sale of Atomoxetine Hydrochloride Capsules, 10 mg (the "Zydus Atomoxetine Capsules") — a generic version of one of the FDA-approved Strattera® Capsule strengths — before the expiration date of the '590 patent.

11. By filing the Zydus ANDA, Zydus has necessarily represented to the FDA that the Zydus Atomoxetine Capsules have the same active ingredient as Strattera®, have the same

route of administration, dosage form, and strength as Strattera®, are bioequivalent to Strattera®, and have the same or substantially the same proposed labeling and use as Strattera®.

12. In the Zydus Notice Letter, Zydus notified Lilly that the Zydus ANDA contains a paragraph IV certification with respect to the '590 patent. Zydus attached to the Zydus Notice Letter a statement asserting its opinion that the '590 patent is invalid. The statement attached to the Zydus Notice Letter does not assert that the Zydus Atomoxetine Capsules would not infringe the '590 patent.

13. This action is being brought before the expiration of forty-five days from the date Lilly received the Zydus Notice Letter.

14. The Zydus ANDA previously sought approval to engage in the commercial manufacture, use, offer to sell, or sale of 18, 25, 40, 60, 80, and 100 mg atomoxetine hydrochloride capsules. On August 16, 2007, Zydus notified Lilly that the previous Zydus ANDA contained a paragraph IV certification with respect to the '590 patent. Zydus attached to that notice letter a statement asserting its opinion that the '590 patent is invalid.

15. On September 5, 2007, Lilly filed Civil Action No. 07-3770 in this Court, alleging, inter alia, that the submission of the Zydus ANDA seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Zydus's proposed atomoxetine hydrochloride capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).

16. In early December of 2007, Zydus abandoned its challenge to Lilly's patent. On December 12, 2007, this Court entered a Consent Order between Lilly and Zydus ("the 2007

Consent Order"), attached at Ex. 2. which enjoined Zydus "from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any of the generic atomoxetine hydrochloride products defined by ANDA 79-017 during the life of the '590 patent, including any extensions . . . ."

17. Zydus expressly stipulated in the 2007 Consent Order that the '590 patent "is neither invalid nor unenforceable." In view of that stipulation, under applicable FDA regulations, Zydus should have amended its ANDA to convert its patent certification from one under "Paragraph IV" (intent to market before patent expiration) to one under "Paragraph III" (intent to market after patent expiration) as a result of the Consent Order.

18. Upon information and belief, after entry of the 2007 Consent Order, Zydus failed to amend its ANDA to convert its patent certification from one under Paragraph IV to one under Paragraph III, in contravention of FDA regulations.

19. Because the life of the '590 patent has not ended, this Court's 2007 Consent Order continues to enjoin Zydus from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic atomoxetine hydrochloride products.

**Count I: Breach of This Court's 2007 Consent Order**

20. Lilly incorporates the preceding paragraphs as if fully set forth herein.

21. Upon information and belief, after entry of the 2007 Consent Order, Zydus knowingly and willfully failed to amend its ANDA to convert its patent certification from one under Paragraph IV to one under Paragraph III, in contravention of FDA regulations. Instead,

after entry of the 2007 Consent Order, Zydus knowingly and willfully filed an ANDA to sell a 10 mg dosage strength of its proposed generic product, in contravention of this Court's Consent Order.

22. Zydus's ANDA filing is and will continue to be done in willful disregard of its obligations under the 2007 Consent Order.

23. As a result of the foregoing facts, Zydus violated the terms of this Court's 2007 Consent Order. Zydus' violation of the Consent Order has created in Lilly a reasonable apprehension of irreparable harm and loss resulting from Zydus's threatened imminent actions.

**Count II: Patent Infringement**

24. Lilly incorporates the preceding paragraphs as if fully set forth herein.

25. Under 35 U.S.C. § 271(e)(2)(A), Zydus's submission of ANDA No. 79-017 to the FDA to obtain approval for the commercial manufacture, use, or sale of the Zydus Atomoxetine Capsules in the United States before the expiration date of the '590 patent constitutes an act of infringement.

26. Upon FDA approval of the Zydus ANDA, Zydus will infringe the '590 patent by making, using, offering to sell, or importing the Zydus Atomoxetine Capsules in the United States, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.

27. On information and belief, Zydus filed ANDA No. 79-017, seeking authorization to commercially manufacture, use, offer for sale, and sell the Zydus Atomoxetine Capsules in the

United States for the treatment of attention-deficit/hyperactivity disorder. On information and belief, Zydus knows that physicians will use the Zydus Atomoxetine Capsules in accordance with the indications sought by Zydus, and will therefore infringe one or more claims of the '590 patent under 35 U.S.C. § 271(b) and/or (c) either literally or under the doctrine of equivalents.

28. On information and belief, Zydus plans to begin marketing, selling, and offering to sell the Zydus Atomoxetine Capsules in the United States soon after the FDA has approved such indications.

29. Zydus had actual knowledge of the '590 patent and had stipulated to the validity of the '590 patent prior to the filing of ANDA No. 79-017. Zydus's threatened manufacture, use, sale, offer for sale and/or importation of the Zydus Atomoxetine Capsules render this case exceptional under 35 U.S.C. § 285 and constitute actual or threatened willful infringement.

30. Zydus's infringing activities complained of herein are imminent and will begin following FDA approval of ANDA No. 79-017.

31. Lilly will be substantially and irreparably harmed by Zydus's infringing activities unless those activities are enjoined by this Court. Lilly has no adequate remedy at law.

**Prayer for Relief**

WHEREFORE, Lilly respectfully requests that this Court enter judgment in its favor as follows:

a) declare that Zydus has violated this Court's 2007 Consent Order by submitting the Zydus ANDA to the FDA prior to the expiration of the '590 patent;

b) declare that the 2007 Consent Order estops Zydus from contesting the validity and enforceability of United States Patent No. 5,658,590;

c) declare that the commercial manufacture, use, offer for sale, sale, or importation of the Zydus Atomoxetine Products would infringe one or more claims of the '590 patent;

d) order that Zydus amend its ANDA No. 79-017 to convert its patent certification from one under Paragraph IV to one under Paragraph III;

e) declare that, under 35 U.S.C. § 271(e)(2)(A), Zydus infringed United States Patent No. 5,658,590 by submitting the Zydus ANDA to the FDA prior to the expiration of the '590 patent;

f) declare that Zydus's commercial manufacture, use, offer for sale, or sale in, or importation into the United States the Zydus Atomoxetine Capsules prior to the expiration of the '590 patent, and its inducement and/or contribution of such conduct by others, will infringe United States Patent No. 5,658,590;

g) order that the effective date of any FDA approval of the Zydus ANDA shall be no earlier than six months after the expiration date of United States Patent No. 5,658,590;

h) enjoin Zydus, and all persons acting in concert with Zydus, from commercially manufacturing, using, offering for sale, or selling the Zydus Atomoxetine Capsules within the United States, or importing the Zydus Atomoxetine Capsules into the United States, until six months after the expiration of United States Patent No. 5,658,590;

i) award Lilly damages or other monetary relief if Zydus engages in the commercial manufacture, use, offer to sell, sale, or importation of the Zydus Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to six months after the expiration of United States Patent No. 5,658,590, and that any such damages or monetary relief be trebled and awarded to Lilly with prejudgment interest;

j) declare this to be an exceptional case and award Lilly its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

k) award Lilly any further appropriate relief under 35 U.S.C. § 271(e)(4); and

l) award Lilly any further and additional relief that this Court deems just and proper.

Dated: May 5, 2011

Respectfully submitted,

ELI LILLY AND COMPANY

By: /s/ John F. Brenner

John F. Brenner
Melissa Chuderewicz
Pepper Hamilton LLP
Suite 400
301 Carnegie Center
Princeton, NJ 08543-5276
Tel: (609) 452-0808
Fax: (609) 452-1147

*Attorneys for Plaintiff*
Eli Lilly and Company

Of Counsel:

Charles E. Lipsey
L. Scott Burwell
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
Two Freedom Square
11955 Freedom Drive
Reston, Virginia 20190-5675
Tel: (571) 203-2700
Fax: (202) 408-4400

Robert D. Bajefsky
Laura P. Masurovsky
Finnegan, Henderson, Farabow
Garrett & Dunner, LLP
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
Tel: (202) 408-4000
Fax: (202) 408-4400